



The University of Georgia

College of Agricultural and Environmental Sciences
Department of Poultry Science

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Dr. Lester Crawford
Acting Director
Food and Drug Administration
5600 Fisher's Lane
Room 1471
Mailstop HF-1
Rockville, MD 20857

Dear Dr. Crawford:

I submitted testimony for the case between Bayer and the Food and Drug Administration regarding the use of enrofloxacin in poultry operations. In reviewing the ruling by the judge in the case, I was extremely disappointed in his evaluation of the information and the conclusions he reached after reviewing the testimony.

As a brief introduction, I am an Associate Professor at the University of Georgia in the Poultry Science Dept. I have extensive experience in poultry processing plant management prior to initiation of my position here at UGA. I have a large extension appointment and have worked with almost every major and minor poultry processor in Canada, the U.S., Mexico, and Central and South America. My area of expertise is poultry microbiology and I have been working in this area for 17 years.

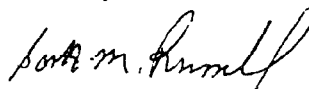
In my testimony, I presented evidence by reporting the results of a research study in which I asked the simple question "are flocks of chickens that have been untreated or unsuccessfully treated for airsacculitis significantly more contaminated with fecal material (resulting from torn intestines) and with *Campylobacter*"? The study was powerful in that it was replicated many times and microbiological samples were encoded and sent to a reference laboratory for evaluation. The results indicated that flocks of chickens that had untreated or unsuccessfully treated air sacculitis infections were significantly higher in fecal contamination and *Campylobacter*. To further support the study, I was able to obtain data collected by a very large local poultry processing plant, representing 32,000,000 birds over a two year period. This company collected data on air sacculitis, fecal contamination, and *Salmonella* prevalence. The data, which was analyzed by the Associate Department Head of Statistics at UGA, demonstrated a significant ($P = 0.0001$) relationship between air sacculitis and fecal contamination, and air sacculitis and *Salmonella* prevalence. All of this data was clearly presented in my testimony; however, the judge threw much of it out. His response was that this case was about *Campylobacter*, not *Salmonella*. As a scientist working in this area for many years, I strongly disagree with his assessment. Both of these pathogens are related to fecal contamination, which results from torn intestines. This case is about the mission of the Food and Drug Administration, which is to ensure the safety of the American food supply. The data contained within this testimony indicates that his ruling is in direct opposition to that which would be prudent in maintaining the safety of the U.S. food supply. I am absolutely convinced that withdrawal of enrofloxacin as a viable antibiotic for treatment of poultry would result in a concomitant increase in food-borne illness and would be ill advised. The study that was submitted by my colleagues as

testimony provides further evidence of this statement. Dr. Hofacre and others found that enrofloxacin was the only commonly used antibiotic that was effective for controlling air sacculitis. Again, in our study, flocks with high air sacculitis had significantly higher *Campylobacter* counts and *Salmonella* prevalence.

Moreover, testimony (stricken) was provided by the Vice President of McDonalds in which he stated that some poultry companies have discontinued using antibiotics and that there has been no adverse affect on the industry. This statement is not only false, but it is extremely misleading. The reason some poultry suppliers chose to discontinue use of antibiotics had nothing to do with food safety. It was a choice they made to maintain good relations with their major customers, such as McDonalds. McDonalds was putting pressure on these producers to discontinue using antibiotics. The reason McDonalds was putting pressure on poultry producers was because of pressure from special interest groups who have little or no understanding of the data that is constantly being produced by the scientific community. Thus, the fundamental reason for discontinued use was not scientific, but a response to a squeaking wheel. Special interest groups often have a narrow view of public safety. They want to impose their will based on unscientific beliefs which, in many cases, are in opposition to the public good. That is why the FDA is so important. It must be objective and evaluate the scientific data when making a decision in an unbiased manner. I believe it has not done so in this case. Additionally, the damage to the industry cannot be assessed immediately. It will take years for poultry companies to understand fully how these changes will impact them. For example, just after removing antibiotics from their feed, a major poultry producer (13 full-scale slaughter facilities) called me into 6 of their plants because they were having severe fecal contamination and the inspectors were writing excessive noncompliance reports. In fact, one plant was shut down while I was visiting. The intestines of these birds were visibly weaker than normal. In these instances, plant management will likely never make the connection between antibiotic withdrawal (which is a corporate decision and is only known to people who work with the growout operation) and weak intestines or fecal contamination. It is far too complex a process for these associations to be made by plant employees. Thus, the company never really has a clear picture of how antibiotic withdrawal affects their total process or food safety. I have had more calls this year to come and assist plants with excessive *Salmonella* prevalence than ever before. I am the only person in the U.S. who is doing this type of work. I believe that withdrawal of antibiotics may be contributing to this problem.

Finally, I am requesting that you bring together a panel of truly independent experts including scientists, poultry professionals, public health specialists, and attorneys to sincerely evaluate the scientific information in an objective way so that appropriate conclusions can be made. I appreciate your consideration in this matter and would be willing to provide any additional information that may be of assistance.

Sincerely,



Scott M. Russell, Ph.D.

Cc: FDA, Dockets Mgmt. Branch